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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SINGH, ANOOP KUMAR	
ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,993	CHANG ET AL.	
	Examiner	Art Unit	
	ANOOP SINGH	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-13,15,18-21,25 and 26* is/are pending in the application.

4a) Of the above claim(s) *16,17 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-13,15,18-21,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on June 4, 2008, has been received and entered. Claims 2-3, 6, 14, 27-66 have been canceled, while applicants have amended claims 1 and 4. A telephone call was made to applicants' representative to inform about the missing claims 19-26 (page 4) in the response filed February 4, 2009. Applicant's complete submission of claim listing filed 2/4/2009 have been received and entered.

Claims 1, 4-5, 7-13, 15-25 and 26 are pending.

Election/Restrictions

Applicant's election with traverse of the invention of claims 1-26 (group I) filed September 18, 2006 was acknowledged. It was noted that applicants elected 2D-CD4 as species for examination in a supplementary response filed on 12/28/2006. It is noted that claims 16-17, 22-24 do not read on elected species and therefore claims 16-17, 22-24 were also withdrawn. Claims 16-17, 22-24 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 18, 2006. The requirement was deemed proper and was therefore made FINAL.

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 are under examination.

Declaration

The Xu declaration filed on February 4, 2009, under 37 CFR 1.132 is sufficient to overcome the rejection of claims 1, 4-5, 11-13 and 25-26, applied under 35 U.S.C. 102(b) as being anticipated by Tagliabue et al (WO 96/11277, IDS, art of record) as evidenced by Steidler et al (US patent 6,190,662, dated 2/20/2001). The declaration will be discussed in detail below as it applies to the rejection.

The Xu declaration filed on February 4, 2009, under 37 CFR 1.132 is sufficient to overcome the rejection of claims 1, 4-5, 7-15, 18, 25 and 26, applied under 35 U.S.C. 103(a) as being unpatentable over Tagliabue et al (WO 96/11277), Steidler et al (US patent 6,190,662, dated 2/20/2001, art of record), Schneewind et al (US patent application, 20060073530, dated 4/6/2006, filing date 8/15/2002, effective filing date 8/15/2001, art of record) and Navarre et al (Microbiol Mol Biol Rev. 1999; 63(1): 174-229, IDS). The declaration will be discussed in detail below as it applies to the rejection.

The Xu declaration filed on February 4, 2009, under 37 CFR 1.132 is sufficient to overcome the rejection of claims 1, 4-5, 7-13, 15, 18-21, 25 and 26, applied under 35 U.S.C. 103(a) as being unpatentable over Tagliabue et al (WO 96/11277, art of record), Steidler et al (US patent 6,190,662, dated 2/20/2001, art of record); Schneewind et al (US patent application, 20060073530, dated 4/6/2006, filing date 8/15/2002, effective filing date 8/15/2001, art of record) Boyd (US 6,193,982, IDS) and Vallor et al. (The Journal of Infectious Diseases, 184:1431-6, 2001, IDS).

Maintained-Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated *Lactobacillus jensenii* bacterium comprising an expression cassette, the expression cassette comprising a promoter operably linked to a polynucleotide encoding a signal sequence and a biologically-active polypeptide, wherein the biologically active

polypeptide is 2D-CD4 that is linked to a heterologous carboxyl terminal cell wall targeting region and wherein the cell wall targeting region comprises SEQ ID NO:7 or SEQ ID NO:8 or variants thereof in which LPQTG (SEQ ID NO:13) in SEQ ID NO:7 or SEQ ID NO:8 is replaced with LPQSG (SEQ ID NO:11), LPQAG (SEQ ID NO:12), or LPQTA (SEQ ID NO:14), wherein the biologically active polypeptide is expressed in the cell wall of the bacterium,

does not reasonably provide enablement for an isolated *Lactobacillus jensenii* comprising expression cassette that does not express protein in the cell wall of the bacterium or *Lactobacillus jensenii* that expresses any biologically active protein other then 2CD4 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is directed to a genetically modified *Lactobacillus jensenii* that is vagina-colonizing strain comprising an exogenous gene encoding the biologically active protein. It is noted that dependent claims limit the cell wall targeting region to that comprising plurality of anchoring sequences.

The invention features methods of creating *Lactobacillus* bacteria comprising an expression cassette, the expression cassette comprising a promoter operably linked to polynucleotide encoding a signal sequence and any biologically-active polypeptide, such that biologically active protein binds to a pathogen when the biologically active protein is contacted with the pathogen. The specification asserts modulating the properties of bacteria within the mucosal flora indented to treat or prevent HIV or Crohn's diseases, as well as related conditions affecting mucosal surfaces (see page 2, para. 8). The specification further contemplates targeting biologically active proteins to the cell wall of these and other organisms that could help to treat such diseases (page 2, para. 6). Thus, in view of foregoing, it is apparent that the only intended purposes of genetically modifying Lactobacillus

jensenii is to display protein on the cell wall of the bacterium or secrete protein to affect mucosal surfaces in the treatment of various disorder.

The aspects considered broad are: *Lactobacillus jensenii* comprising expression cassette that does not express protein in the cell wall to make use of the invention. The instant specification and the prior art provide sufficient guidance to indicate that surface expression of proteins via covalent linkage with peptidoglycans in Gram-positive bacteria involves unique sorting signals and sortase-dependent machinery. The prior art also teaches plurality of genetically modified bacterium for the expression of biologically active protein (see US patent 6,190,662, dated 2/20/2001 and WO 96/11277, art of record). The specification teaches that the all the three cell wall anchored proteins identified after genomic sequencing of *L. jensenii* 1153 have LPQTG sorting signal preceding a hydrophobic region and a charged C-terminal tail and possess unique long repetitive sequences (see figure 1 of the specification). In addition, instant specification has exemplified a stretch of 95 amino acids containing one tandem repeat in fusion with the C-terminal cell wall sorting signal in pOSEL268 (Examples and see Figure 7) enables surface display of CD4 in *Lactobacillus jensenii*. The specification provides guidance with respect to an isolated *Lactobacillus jensenii* (emphasis added) comprising an expression cassette comprising a promoter operably linked to polynucleotide encoding a signal sequence and a biologically active polypeptide, wherein the biologically active polypeptide is 2CD4 linked to a heterologous carboxyl terminal cell wall targeting region. Claims 1, 4-5, 7-12, 18-21, 25 and 26 embrace a genetically modified *Lactobacillus jensenii* that is intended for the treatment of variety of viral infections. The specification contemplates that "biologically active protein" refers to any amino acid sequence that has the biological activity of the amino acid sequence within, or outside of, a native cell (see para 35 of the published application). In addition, specification contemplates polypeptides of the invention can be of any size and molecular weight (See para. 112). The specification has exemplified

Lactobacillus jensenii expressing 2-CD4 on the surface (see example and para 115 of the published application). In the instant case, as recited instant claims do not require expression of any protein at the cell wall of the bacterium. It is apparent from the cited arts that biological function of a protein, peptide or its fragments were unpredictable at the time of the invention and even same short stretch of amino acid sequence could show diverse biological functions while surrounded by different background amino acid sequences. Prior to instant invention, Davis, (New Biologist, 1990, 2(5), 410-419, art of record) teaches that EGF repeats appears in an extraordinarily diverse group of molecules, including growth factors, transmembrane molecules, extracellular matrix proteins, and soluble secreted proteins, and it is often difficult to deduce what contribution the EGF repeat makes in a totally unrelated protein (e.g. p. 410, left column). It appears that EGF repeat can contribute to different biological functions in different amino acid. In the instant case, the *Lactobacillus* surface require expression of polypeptide molecules at level sufficient that are evenly distributed in the correct conformation to affect mucosal tissue or bind pathogen to exert its intended use.

The specification provides guidance with respect to a genetically modified *Lactobacillus jensenii* comprising an expression cassette comprising a promoter operably linked to polynucleotide encoding a signal sequence and a biologically active polypeptide, wherein the biologically active polypeptide is 2CD4 linked to a heterologous carboxyl terminal cell wall targeting region. However, it does not provide specific information required by the Artisan to reasonably predict a *Lactobacillus jensenii* comprising any biologically active protein inserted into the cell wall will express the protein at the surface and not adversely affect the assembly of the cell wall. Applicants do not enable a *L. jensenii* expressing plurality of biologically active polypeptide in the cell wall of the bacterium. The specification contemplates biologically active protein refers to any amino acid sequence that has the biological activity of the amino acid sequence within, or outside of, a native cell

(see para 35 of the published application). In addition, specification contemplates polypeptides of the invention can be of any size and molecular weight (See para. 112). The specification has exemplified *Lactobacillus jensenii* expressing 2-CD4 on the surface (see example and para 115 of the published application). Prior to instant invention, it is art recognized that protein folding affects the biological activity and the tertiary structure of a protein adopting a native conformation is not predictable that will require further guidance (Ngo et al., 1994, The protein Folding Problem and Tertiary Structure Prediction, pp492-495, art of record). In a post filing art Baneyx et al (Microbial Cell Fact., 2004,3 (6) 1-2) state '[i]t is now well established that many proteins require the assistance of folding modulators to adopt a native structure as they emerge from ribosomes, regain their original conformation following exposure to stress, or traffic to their ultimate destination" (see page 1, col.1, para. 1). The art further teaches that bacteria are unable to carry out most of the posttranslational modifications that are often required for eukaryotic protein function. It is noted that Villaverde et al (Biotechnology Letters, 2003, 25: 1385–1395) reported that '[d]espite functional protein can be still recovered by *in vitro* preparative refolding from inclusion bodies, the process optimization for a given protein species involves time-consuming efforts with results that being irregular". In the instant case, neither specification nor prior art teaches displaying any polypeptide other then 2D-CD4 on the bacterial cell surface in correct conformation at level sufficient to exert its biological effect in treating or preventing the mucosal disease. The specification teaches identifying two sequences $RKKRQK1_{765}$ and $KKKRKDDEA_{1903}$ as the positive charged tails in C14 and C370 putative anchor sequences respectively (see figure 1) to serve as cell surface retention signal. The specification concurs that the cell wall-anchored proteins in gram-positive bacteria contain a characteristic stretch of positively charged amino acids at the extreme C terminus. These signature charged sequences serve as a critical cell surface retention signal. In the instant case, specification teaches that deletion of the

positively charged C-termini of both C14 and C370 inhibited their ability to anchor to the cell wall and display heterologous proteins. It is apparent that as recited *Lactobacillus jensenii* set forth in claims 1, 4-13, 15, 18-21, 25-26 embrace a bacterium wherein polypeptide would not be anchored to the cell wall and display heterologous proteins required for intended biological effect.

The applicant's disclosure does not enable one skilled in the art to make use of the invention commensurate with full scope without further undue amount of experimentation, which requires the expression of plurality of different protein in correct conformation at level sufficient at the surface of the isolated *Lactobacillus jensenii* such that it shows contemplated biological activity. The specification is silent of any other surface-anchored protein that is recognized by a conformation-dependent antibody suggesting that the expressed proteins would adopt a native conformation.In the instant case, specification read on expressing genus of biologically active protein including GFP, albumin, Factor VIII, but fails to disclose enabling use of such recombinant *Lactobacillus jensenii* . Absent of evidence to the contrary, it is not clear that whether any biologically active protein of any size would be functional in correct conformation at level sufficient in the cell wall in same manner as they have been demonstrated for 2D-CD4, particularly since claims 1, 4-5, 7-12, 18-21, 25 and 26 do not require expression of the protein on the cell wall of the bacterium. An artisan would have to perform undue experimentation to empirically test by trial and error different nucleic acid encoding protein to practice the *L. jensenii* comprising diverse group of biologically active protein such that it is expressed at the surface intended for the treatment of variety of disease to make use of the invention without reasonable expectation of success.

In conclusion, in view of breadth of the claims and absence of specific guidance and direction, and/or working examples demonstrating the same, such invention as claimed by applicant is not enabled for using any isolated genetically Lactobacillus jensenii that do not express biologically active polypeptide in the cell

wall of the bacterium . The specification and prior art enables "an isolated Lactobacillus jensenii bacterium comprising an expression cassette, the expression cassette comprising a promoter operably linked to polynucleotide encoding a signal sequence and a biologically-active polypeptide, wherein the biologically active polypeptide is 2CD4 that linked to a heterologous carboxyl terminal cell wall targeting region and wherein the cell wall targeting region comprises SEQ ID NO:7 or SEQ ID NO:8 or variants thereof in which LPQTG (SEQ ID NO:13) in SEQ ID NO:7 or SEQ ID NO:8 is replaced with LPQSG (SEQ ID NO:I 1), LPQAG (SEQ ID NO:12), or LPQTA (SEQ ID NO:14), wherein the biologically active polypeptide is expressed in the cell wall of the bacterium.

Withdrawn-Claim Rejections - 35 USC § 112

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 were rejected under 35 U.S.C. 112, second paragraph. Applicants' amendments to the claims overcome the rejection of record. Therefore, rejection is hereby withdrawn.

Withdrawn-Claim Rejections - 35 USC § 102

Claims 1, 4-5, 11-13 and 25-26 were rejected under 35 U.S.C. 102(b) as being anticipated by Tagliabue et al (WO 96/11277, IDS, art of record) as evidenced by Steidler et al (US patent 6,190,662, dated 2/20/2001). Applicants' arguments and declaration by Dr. Xu is persuasive to the extent Examiner would agree that prior art did not disclose a *Lactobacillus jensenii* comprising an expression cassette comprising a promoter operably linked to a polynucleotide encoding a signal sequence and a biologically active polypeptide that is linked to a heterologous carboxyl cell wall targeting region. Therefore, rejection is hereby withdrawn.

Claims 1, 4-5, 7-15, 18-21, 25 and 26 were rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (US 7179,458, dated 2/20/2007, effective filing date 3/8/2002) or Chang et al (US patent application number US 2007/0117197, dated 5/24/2007, effective filing date 3/8/2002, now US Patent 7, 312,076,daed 12/25/07).

Applicants' argument that the Chang priority provisional application 60/362,945 does not teach SEQ ID NO: 7 or 8 are persuasive. Therefore, rejection is hereby withdrawn.

Withdrawn-Claim Rejections - 35 USC § 103

Claims 1, 4-5, 7-15, 18, 25 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tagliabue et al (WO 96/11277), Steidler et al (US patent 6,190,662, dated 2/20/2001, art of record), Schneewind et al (US patent application, 20060073530, dated 4/6/2006, filing date 8/15/2002, effective filing date 8/15/2001, art of record) and Navarre et al (Microbiol Mol Biol Rev. 1999; 63(1): 174-229, IDS). Applicants' argument and declaration by Dr. Xu is persuasive to the extent Examiner would agree that cited references do not provide reasonable expectation of success in using variants of SEQ ID NO: 7 or 8 in expressing polypeptide on the surface of bacterium. Therefore, rejection is hereby withdrawn.

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Tagliabue et al (WO 96/11277, art of record), Steidler et al (US patent 6,190,662, dated 2/20/2001, art of record); Schneewind et al (US patent application, 20060073530, dated 4/6/2006, filing date 8/15/2002, effective filing date 8/15/2001, art of record) Boyd (US 6,193,982, IDS) and Vallor et al. (The

Journal of Infectious Diseases, 184:1431-6, 2001, IDS). The rejection is withdrawn for the reason discussed above.

Maintained- Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 11/620,588 (now US Patent 7,312,076). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a *Lactobacillus jensenii* bacterium recombinantly altered to express any biologically active protein when it is contacted with a pathogen. Furthermore, '588 also discloses anchor sequences that are located at the carboxyl terminus of an encoded

protein sequence that includes a cell wall associated sequence; the sequence LPQ(S/A/T)(G/A), where residues in parentheses indicate different options at that position; and a hydrophobic sequence, and, optionally, a charged sequence. The anchoring sequence comprises SEQ ID NO:4 or 5. It is noted that claims of '588 claims differ only with respect to a broader scope of biologically active protein and specific elements to recombinantly alter bacterium set forth in claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 that are broadly encompassed those specifically claimed in claims 1-12 of '588. Therefore, the claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 of the instant application are embraced by claims 1-12 of co-pending application '588.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/331,965 (now US patent 7,456011). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a *Lactobacillus jensenii* bacterium recombinantly altered to express any biologically active protein when it is contacted with a pathogen. It is noted that claims of '965 claims differ only with respect to a broader scope of biologically active protein and specific elements to recombinantly alter bacterium set forth ion claims 1, 4-5, 7-13, 15, 18-21, 25 and 26 are broadly encompassed those specifically claimed in claims 1-2 of '965. Therefore, the claims 1-5, 7-15, 18-21, and 25-26 of the instant application are encompassed by claims 1-2 of co-pending application '965.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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